

**REMARKS**

In a May 2, 2006 Preliminary Amendment, new Claims 34-50 were added. Claims 1-23 and 33 were subsequently cancelled. Claims 37, 39 and 40 were subsequently withdrawn. In the May 29, 2007 Amendment, Claim 51 was added. New Claim 52 is presently added. Accordingly, Claims 24-32, 34-36, 38 and 41-52 are currently pending. Claim 24 is the only independent claim.

Accompanying this Amendment is an unexecuted declaration by Dr. Rainer Gruening. An executed declaration will follow shortly.

**Rejection under 35 U.S.C. §103 in view of *Beckman***

Claims 24-32, 34-36, 38 and 41-50 are rejected under 35 U.S.C. §103 as being obvious over *Beckman et al.* (U.S. Patent Application No. 2002/0015697, hereinafter "*Beckman*"). (See Office Action pages 4-5.)

*Beckman* provides a method for reducing a microbial population on a surface with a composition that comprises a transition metal as the active ingredient. In particular, *Beckman* state that its compositions reduce microbial populations by causing a "transition metal overload." (See paragraph [0040] of *Beckman*.) That is, *Beckman* requires a transition metal for reducing microbial populations. Along with the transition metal, the *Beckman* composition includes a non-oxidant stress inducer such as chitosan.

The pending claims recite a method of inhibiting the intrusion of micro-organisms into a body cavity of a mammal by applying a "**fully reversible**" **hydrogel** composition. The hydrogel is a lubricious aqueous gelatinous composition. The hydrogel comprises a poly(N-vinyl lactam), a polysaccharide and water.

The polyvinyl lactam and the polysaccharide of the hydrogels are present in a specific ratio. Independent Claim 24 has been amended so that the range of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide is about 5 : 1 to about 75 : 1. Support for this amendment is Claim 30.

Independent Claim 24 has also been amended to emphasize that the hydrogels of the present invention are “fully reversible.” Support for this amendment is throughout the specification including page 9, lines 11-15. Some of the characteristics of the “fully reversible” hydrogels are described on page 15, lines 18-23. There, it is stated that the hydrogels “break apart” when forced through small holes, and then “surprisingly” reform.

Dr. Gruening further elaborates on the rheological behavior of the “fully reversible” hydrogels in his declaration. In particular, he states:

[T]he hydrogels of the instant invention are unexpectedly fully reversible. In particular, the hydrogels break apart when forced through small holes, and then surprisingly recombine. Broken apart, the hydrogels form pieces with course/rough-appearing surfaces and uneven break lines. It is believed that the hydrogen bonds in these hydrogels are temporarily broken when such hydrogels are forced through small holes of applicators. The hydrogen bonds fuse together again after a few hours. (See paragraph 5 of the Gruening Declaration.) (Emphasis added.)

The Examiner states that “*Beckman*’s compositions can be in the form of gels” (Office Action page 7, last paragraph.)

However, the only mention by *Beckman* of any type of gel is at paragraph [0058]. The only type of gel mentioned by *Beckman* is “viscous gels.” A “viscous gel” has completely different physical characteristics and completely different rheological behavior *vis-à-vis* the “fully reversible” hydrogels of the present invention.

According to Dr. Rainer Gruening, unlike the “fully reversible” hydrogels of the present invention, the “viscous gels” do not “break apart” when forced through small holes. Instead the surfaces of the “viscous gels” would remain “smooth” as they pour through small holes. On a molecular level, instead of hydrogen bonds breaking up as in the “fully reversible” hydrogels of the present invention, the “viscous gels” “tend to result in ‘long strings’ of polymers when poured.” (See paragraph 8 of the Gruening Declaration.)

**Thus, the “viscous gels” disclosed by Beckman are not equivalent structurally or rheologically to the “fully reversible” hydrogels of the present invention.** It is apparent that *Beckman* did not even contemplate fully reversible hydrogels.

According to Dr. Rainer Gruening, the unique characteristics of the compositions of the present invention were unpredictable and unexpected at the time of the present invention. In particular, the formation of the “fully reversible” hydrogels from the constituent ingredients was unpredictable. (See paragraphs 4, 5 and 11 of the accompanying declaration.) Additionally, the “sanitizing and disinfecting activity” demonstrated by the hydrogels “without the inclusion antimicrobials/antibiotics” was also unpredictable at the time of the present invention. (See paragraph 4 of the accompanying declaration.)

The Examiner states that;

Generally, mere optimization of ranges will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration ...is critical.  
(Office Action page 8, 1<sup>st</sup> full paragraph.)

“The specific ratios of the constituent ingredients” of the compositions of the present invention are critical. Without such ratios, the “fully reversible” hydrogels would not form. (See paragraph 4 of the accompanying declaration.)

The Examiner also states that;

The normal desire of scientists and artisans to improve upon what is already known provides motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.  
(Office Action page 8, 1<sup>st</sup> full paragraph.) (Emphasis added.)

The present invention as recited in the pending claims is not merely an improvement of the *Beckman* composition. The “fully reversible” hydrogels of the present invention are a completely different *type* of composition than the *Beckman* composition. The *Beckman* “viscous gels” are completely structurally and rheologically different from the “fully reversible” hydrogels of the present invention. Thus, it was not a matter of optimizing ratios of ingredients. Instead, a skilled artisan would not have expected to produce the “fully reversible” hydrogels of the present invention. The difference between the *Beckman* compositions and the hydrogels of the present invention is a difference in kind, i.e., not a difference in degree.

It is apparent that *Beckman* did not even contemplate “fully reversible” hydrogels. The active ingredient of the *Beckman* composition is a transition metal. Chitosan is also added. The additional of polyvinylpyrrolidone (PVP) at paragraph [0145] is merely optional. *Beckman* clearly does not teach adding PVP in the relative large amount described in the present invention. In the pending claims, PVP is the bulk of the “fully reversible” hydrogels.

Moreover, the specific ratios necessary to form the “fully reversible” hydrogels could not have been predicted at the time of the invention. (See paragraphs 4, 5 and 11 of the accompanying declaration.)

Section 2143 of the MPEP provides guidelines to determine if a claimed invention is obvious in the wake of *KSR International Co. v. Teleflex, Inc.* (82 USPQ2d 1385 (2007)). There, rationale that may be used by an examiner to support a conclusion of obviousness are listed from A to G.

In order for an examiner to conclude an invention is obvious under Rationale A, B and D-F, the results of the invention are required to be “predictable” in view of the prior art reference. As discussed above, the resulting “fully reversible” hydrogels could not have been predicted. Thus, the subject matter of the pending claims can not be obvious under Rationale A, B and D-F.

Under Rationale C, obviousness may be found if known techniques are used “to improve similar...products...in the same way.” As discussed above, the resulting “fully reversible” hydrogels of the present invention are not improving the *Beckman* composition “in the same way.” Instead, compositions that are completely different rheologically and physically are produced. Thus, the subject matter of the pending claims can not be obvious under Rationale C.

Under Rationale G, obviousness may be found if “[s]ome teaching, suggestion, or motivation in the prior art...would have led one of ordinary skill to modify the prior art reference...to arrive at the claimed invention.” As discussed above, there is nothing in *Beckman* that teaches, suggests or motivates one to produce a “fully reversible” hydrogel. Moreover, *Beckman* teaches that a transition metal is required in order to have antimicrobial properties. The whole purpose of the *Beckman* is to deliver the antimicrobial transition metal. In contrast, the “fully reversible” hydrogels of the present invention intrinsically have antimicrobial properties. Accordingly, *Beckman* teaches away from the hydrogels of the present invention. Thus, the subject matter of the pending claims can not be obvious under Rationale G.

Accordingly, Applicants request withdrawal of this obviousness rejection.

**Rejection under 35 U.S.C. §103 *Beckman* in view of *Stoner***

Claim 51 is rejected under 35 U.S.C. §103 as being obvious over *Beckman* in view of U.S. Patent No. 4,925,033 (hereinafter “*Stoner*”). (See Office Action pages 6.)

Since the claim upon which Claim 51 depends is not obvious over *Beckman*, as discussed above, the further disclosure by *Stoner* does not render Claim 51 obvious. Accordingly, Applicants request withdrawal of this obviousness rejection.

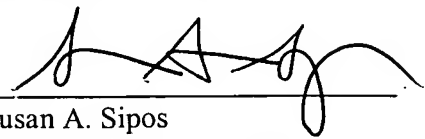
**New Claim 52**

New Claim 52 depends on Claim 24 and further limits the lower boundary of the ratio of the amount by weight of the poly(N-vinyl) lactam to the amount by weight of the polysaccharide. Support for this claim is in original Claim 30. No new matter was added.

Applicants do not believe that any fees are due other than those for the petition for the extension of time and the Notice of Appeal. However, if any other fees are due, please deduct such sum from Deposit Account No. 08-2461.

Applicants respectfully submit that the application is in all respects complete and in condition for allowance. If the Examiner has any questions or comments, it is respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,



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